Health & Human Resources Committee Amendment No. 1

Amendment No. 1 to HB1056

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Senate Bill No. 1209 AMEND

House Bill No. 1056*

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 6, Part 2, is amended by adding the following new section:

Section 63-6-2 .

- (a) For the purposes of this section:
- (1) "Office-based surgery" means Level III surgery requiring a level of sedation beyond the level of sedation defined by the board of medical examiners as Level II surgery that is performed outside a hospital, an ambulatory surgical treatment center, or other medical facility licensed by the department of health;
 - (2) "Board" means the board of medical examiners;
- (3) "Physician" means any person licensed under chapter 6 of this title.
- (4) "Surgical suite" means both the operating and recovery room(s) located in a physician's office wherein Level III office-based surgery is to be performed.
- (b) The board shall have the duty and responsibility to regulate the practice of office-based surgery, including the promulgation of rules necessary to promote patient health and safety in such practices including, but not limited to, a mechanism by which all office-based surgical suites are surveyed and certified by the board.
- (c) The board shall specifically identify in rules the parameters to be used in determining Level III surgical procedures and multiple procedures that may be performed in an office-based setting pursuant to the level of anesthesia involved

in such procedures. In addition, the board shall promulgate age and risk classification criteria of patients eligible for Level III office-based surgical procedures.

- (d) Within ninety (90) days of the effective date of this act, the board shall adopt rules establishing a specific list of approved Level III surgical procedures that can be performed in a physician's office in this state. The Ambulatory Surgical Center Covered Procedures List promulgated by the Centers of Medicare and Medicaid, as amended from time to time, shall be used as a guide. No physician shall perform any Level III surgical procedures that are not included on the list promulgated by the board. The board may modify the list as the board deems necessary. The board shall also promulgate rules addressing the minimum requirements deemed necessary by the board for the safe performance of office-based surgery.
- (e) Using the rules established for ambulatory surgical treatment centers as guidelines, the board shall promulgate rules relative to infection control, life safety, patient rights, hazardous waste and equipment and supplies necessary to assure the safety of patients undergoing office-based surgery. Any provision in the ambulatory surgical treatment center rules addressing infection control, life safety, patient rights, hazardous waste and equipment and supplies that is not adopted by the board shall require a statement entered into the official minutes from the board justifying the board's decision.
- (f) No more than three (3) patients in a physician's office undergoing

 Level III office-based surgery may be incapable of self-preservation at the same

 time. The board shall promulgate rules requiring physician offices that perform

 office-based surgery to adopt bylaws that put in place a management system and
 documentation that will insure that no more than three (3) patients that are in

 surgery or recovery are incapable of self-preservation at the same time. Such

 by-laws and documentation of the management system shall be included in the

application for surgical suite certification.

- (g) Except for emergencies, a surgical suite certified for office-based surgery may be utilized only by physician employees of the practice in which the surgical suite is located. Surgical suites may not be shared with other practices or other physicians.
- (h) The board shall enter into a memorandum of understanding, contract or other written arrangement with the department of health such that the department:
 - (1) Shall provide a site survey of the surgical suites sought to be certified to perform office-based surgery. A physician office at which office-based surgeries are being performed as of the effective date of this act shall submit both a request for a site survey on an application form developed by the board and remit payment of the office-based surgery fee to the department by the effective date of this act. If such office makes a timely filling in accordance with this provision, the physician's office may continue to be a site for office-based surgeries pending completion of a survey confirming compliance with board rules and subsequent issuance of a certification of the surgical suite(s). A physician office at which office-based surgeries are not being performed as of the effective date of this act shall not perform any such procedures until an application form and payment of the office-based surgery fee is submitted to the board and a site survey is completed by the department and a certification of the surgical suite is issued by the board.
 - (2) Is authorized to require plans of correction and to verify that the plans of correction have been implemented.
 - (3) Is authorized to initiate subsequent, unannounced site surveys during regular business hours as long as the physician office continues to be used to perform office-based surgeries but no more frequently than

once every 12 months.

- (4) Is authorized to respond to any complaints made by patients or the public against a physician who performs office-based surgery or a physician's office at which office-based surgery is being performed at the request of the office of investigations.
- (i) The results of all site surveys shall be transmitted by the department to the board. The results shall include any requirement for plans of correction, the department's determination of the acceptability of the submitted plans of correction, and the department's verification that the plans of correction have been implemented. The board shall make a final determination on certifying the surgical suite for performance of office-based surgeries. The results of site surveys and board determinations shall be shared on a routine basis with the board for licensing health care facilities.
- (j) The results of all complaint investigations by department staff shall be transmitted to the board for resolution. However, such information shall at all times be maintained as confidential and not available to the public except to the extent the provisions of Section 63-1-117(b) apply.
- (k) Any physician office that desires to be certified to perform office-based surgery shall pay to the department an annual office-based surgery fee as set by the board.
- (I) A physician office at which office-based surgery is being performed shall insure that claims data is reported to the commissioner of health on a form approved by the department of health. The data shall be submitted through a third party approved by the department of health for the purpose of editing the data according to rules and regulations established by the commissioner. The physician office shall be responsible for the costs associated with processing of the data by the approved vendors. The claims data shall be reported at least quarterly to the commissioner. No information shall be made available to the

public by the commissioner that reasonably could be expected to reveal the identity of any patient. The claims data reported to the commissioner under this section are confidential and not available to the public until the commissioner processes and verifies such data. The commissioner shall prescribe conditions under which the processed and verified data are available to the public.

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- (1) Except as provided in subdivision (h)(1), a physician office surgical suite is required to be certified by the board in order to perform office-based surgery. For each physician that proposes to perform office-based surgery the physician must submit to the board, on an application form provided by the board, at least the following:
 - (A) Level III procedures expected to be performed;
 - (B) The specialty board certification or board eligibility of the physician(s) performing Level III procedures, if any;
 - (C) Verification of medical malpractice coverage for all physicians performing Level III procedures;
 - (D) Verification of hospital staff privileges for all physicians performing Level III procedures;
 - (E) The name of a responsible physician in whose name the surgical suite certification shall be issued for that office and a list of the physicians with the practice that are going to be performing Level III office-based surgeries; and
 - (F) The documentation required by subsection (f) regarding incapacitated patient limits.
- (2) The form required by this subsection shall serve as an application form but the information on the form must be updated as appropriate when any information on it has changed.
- (n) The board shall notify all physicians of the office-based surgery

certification requirements. Failure of a physician performing office-based surgery, or a physician office at which office-based surgery is being performed to abide by the provisions of this section, any rules promulgated pursuant to this section, or of Section 68-11-211 may be grounds for disciplinary action and/or termination of either the rights of the physician to perform office-based surgery or the surgical suite's certification by the physician's licensing board. For purposes of section 4-5-320(c) the public health, safety and welfare will imperatively require emergency action at any time a previously authorized surgical suite fails to maintain the standards set by the board.

SECTION 2. Tennessee Code Annotated, Section 68-11-211(c), is amended by deleting subdivision (4) in its entirety and substituting the following:

(4) "Facility" is any facility licensed under this part and any physician's office where Level III office-based surgery occurs.

SECTION 3. Tennessee Code Annotated, Section 68-11-211(d), is amended by deleting the last sentence of subdivision (1) in its entirety and substituting the following:

The provisions of this subsection (d) and of Section 68-11-804(c)(23) shall not affect any of the provisions of or limit the protections provided by Section 63-6-219 and Section 63-9-114.

SECTION 4. Tennessee Code Annotated, Section 68-11-211(d), is amended by adding the following sentence at the end of subdivision (6):

Notwithstanding the provisions of the previous sentence, the resolution of any disagreement between the department and a physician performing Level III office-based surgery shall be made by the physician's licensing board pursuant to any dispute resolution mechanism available to the licensing board.

SECTION 5. Tennessee Code Annotated, Title 63, Chapter 9, Part 1, is amended by adding the following new section:

Section 63-9-1 .

(a) For the purposes of this section:

- (1) "Office-based surgery" means Level III surgery requiring a level of sedation beyond the level of sedation defined by the board of medical examiners as Level II surgery that is performed outside a hospital, an ambulatory surgical treatment center, or other medical facility licensed by the department of health;
 - (2) "Board" means the board of osteopathic examination;
- (3) "Physician" means any person licensed under chapter 9 of this title.
- (4) "Surgical suite" means both the operating and recovery room(s) located in a physician's office wherein Level III office-based surgery is to be performed.
- (b) The board shall have the duty and responsibility to regulate the practice of office-based surgery, including the promulgation of rules necessary to promote patient health and safety in such practices including, but not limited to, a mechanism by which all office-based surgical suites are surveyed and certified by the board.
- (c) The board shall specifically identify in rules the parameters to be used in determining Level III surgical procedures and multiple procedures that may be performed in an office-based setting pursuant to the level of anesthesia involved in such procedures. In addition, the board shall promulgate age and risk classification criteria of patients eligible for Level III office-based surgical procedures.
- (d) Within ninety (90) days of the effective date of this act, the board shall adopt rules establishing a specific list of approved Level III surgical procedures that can be performed in a physician's office in this state. The Ambulatory Surgical Center Covered Procedures List promulgated by the Centers of Medicare and Medicaid, as amended from time to time, shall be used as a guide. No physician shall perform any Level III surgical procedures that are not included

on the list promulgated by the board. The board may modify the list as the board deems necessary. The board shall also promulgate rules addressing the minimum requirements deemed necessary by the board for the safe performance of office-based surgery.

- (e) Using the rules established for ambulatory surgical treatment centers as guidelines, the board shall promulgate rules relative to infection control, life safety, patient rights, hazardous waste and equipment and supplies necessary to assure the safety of patients undergoing office-based surgery. Any provision in the ambulatory surgical treatment center rules addressing infection control, life safety, patient rights, hazardous waste and equipment and supplies that is not adopted by the board shall require a statement entered into the official minutes from the board justifying the board's decision.
- (f) No more than three (3) patients in a physician's office undergoing Level III office-based surgery may be incapable of self-preservation at the same time. The board shall promulgate rules requiring physician offices that perform office-based surgery to adopt bylaws that put in place a management system and documentation that will insure that no more than three (3) patients that are in surgery or recovery are incapable of self-preservation at the same time. Such by-laws and documentation of the management system shall be included in the application for surgical suite certification.
- (g) Except for emergencies, a surgical suite certified for office-based surgery may be utilized only by physician employees of the practice in which the surgical suite is located. Surgical suites may not be shared with other practices or other physicians.
- (h) The board shall enter into a memorandum of understanding, contract or other written arrangement with the department of health such that the department:
 - (1) Shall provide a site survey of the surgical suites sought to be

certified to perform office-based surgery. A physician office at which office-based surgeries are being performed as of the effective date of this act shall submit both a request for a site survey on an application form developed by the board and remit payment of the office-based surgery fee to the department by the effective date of this act. If such office makes a timely filing in accordance with this provision, the physician's office may continue to be a site for office-based surgeries pending completion of a survey confirming compliance with board rules and subsequent issuance of a certification of the surgical suite(s). A physician office at which office-based surgeries are not being performed as of the effective date of this act shall not perform any such procedures until an application form and payment of the office-based surgery fee is submitted to the board and a site survey is completed by the department and a certification of the surgical suite is issued by the board.

- (2) Is authorized to require plans of correction and to verify that the plans of correction have been implemented.
- (3) Is authorized to initiate subsequent, unannounced site surveys during regular business hours as long as the physician office continues to be used to perform office-based surgeries but no more frequently than once every 12 months.
- (4) Is authorized to respond to any complaints made by patients or the public against a physician who performs office-based surgery or a physician's office at which office-based surgery is being performed at the request of the office of investigations.
- (i) The results of all site surveys shall be transmitted by the department to the board. The results shall include any requirement for plans of correction, the department's determination of the acceptability of the submitted plans of correction, and the department's verification that the plans of correction have

been implemented. The board shall make a final determination on certifying the surgical suite for performance of office-based surgeries. The results of site surveys and board determinations shall be shared on a routine basis with the board for licensing health care facilities.

- (j) The results of all complaint investigations by department staff shall be transmitted to the board for resolution. However, such information shall at all times be maintained as confidential and not available to the public except to the extent the provisions of Section 63-1-117(b) apply.
- (k) Any physician office that desires to be certified to perform office-based surgery shall pay to the department an annual office-based surgery fee as set by the board.
- (I) A physician office at which office-based surgery is being performed shall insure that claims data is reported to the commissioner of health on a form approved by the department of health. The data shall be submitted through a third party approved by the department of health for the purpose of editing the data according to rules and regulations established by the commissioner. The physician office shall be responsible for the costs associated with processing of the data by the approved vendors. The claims data shall be reported at least quarterly to the commissioner. No information shall be made available to the public by the commissioner that reasonably could be expected to reveal the identity of any patient. The claims data reported to the commissioner under this section are confidential and not available to the public until the commissioner processes and verifies such data. The commissioner shall prescribe conditions under which the processed and verified data are available to the public.

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(1) Except as provided in subdivision (h)(1), a physician office surgical suite is required to be certified by the board in order to perform office-based surgery. For each physician that proposes to perform office-

based surgery the physician must submit to the board, on an application form provided by the board, at least the following:

- (A) Level III procedures expected to be performed;
- (B) The specialty board certification or board eligibility of the physician(s) performing Level III procedures, if any;
- (C) Verification of medical malpractice coverage for all physicians performing Level III procedures;
- (D) Verification of hospital staff privileges for all physicians performing Level III procedures;
- (E) The name of a responsible physician in whose name the surgical suite certification shall be issued for that office and a list of the physicians with the practice that are going to be performing Level III office-based surgeries; and
- (F) The documentation required by subsection (f) regarding incapacitated patient limits.
- (2) The form required by this subsection shall serve as an application form but the information on the form must be updated as appropriate when any information on it has changed.
- (n) The board shall notify all physicians of the office-based surgery certification requirements. Failure of a physician performing office-based surgery, or a physician office at which office-based surgery is being performed to abide by the provisions of this section, any rules promulgated pursuant to this section, or of Section 68-11-211 may be grounds for disciplinary action and/or termination of either the rights of the physician to perform office-based surgery or the surgical suite's certification by the physician's licensing board. For purposes of section 4-5-320(c) the public health, safety and welfare will imperatively require emergency action at any time a previously authorized surgical suite fails to maintain the standards set by the board.

SECTION 6.

- (a) The board of medical examiners is authorized to promulgate public necessity rules necessary to carry out the provisions of this act in accordance with the provisions of the Uniform Administrative Procedures Act compiled in title 4, chapter 5.
- (b) The board of osteopathic examination is authorized to promulgate public necessity rules necessary to carry out the provisions of this act in accordance with the provisions of the Uniform Administrative Procedures Act compiled in title 4, chapter 5.

SECTION 7. This act shall take effect upon becoming law for the purposes of promulgating rules and shall take effect on October 1, 2007 for all other purposes, the public welfare requiring it.